DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

9207d

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

November 23, 2001

WARNING LETTER
CHI-10-02

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Lee N. Mugnolo, President/CEO
J.M.C. Ltd. d.b.a. Racconto
2000 Hawthorne St.
Melrose Park, IL 60160

Dear Mr. Mugnolo:

On August 3, 7, and 9, 2001, the Food and Drug Administration (FDA) conducted an inspection of your facility. The inspection was conducted to determine your compliance with FDA's seafood processing regulations (Title 21, Code of Federal Regulations (CFR), Part 123).

The seafood processing regulations, which became effective on December 18, 1997, require that you have and implement written verification procedures to verify that your foreign suppliers have implemented a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP) in accordance with U.S. requirements. These verification procedures must include product specifications to preclude safety hazards and at a minimum one or more affirmative steps [21 CFR 123.12(a)(2)(ii)]. Affirmative steps may include the following:

(A) Obtain from the foreign processor the HACCP and sanitation monitoring records that relate to the specific lot offered for import;

(B) Obtain either a continuing or lot-by-lot certificate from an appropriate foreign government or third party;

(C) Regularly inspect the foreign processor's facilities;

(D) Maintain on file a copy, in English, of the foreign processor's HACCP plan, and a written guarantee from the foreign processor that the imported fish or fishery product was processed in accordance with seafood HACCP;

(E) Periodically test the imported fish or fishery product, and maintain on file, in English, a written guarantee from the foreign processor that the imported fish or fishery product was processed in accordance with seafood HACCP; and

(F) Other such verification measures as appropriate that provide an equivalent level of assurance of compliance with the requirements of this part.

These are the kinds of measures that prudent importers already take. HACCP provides a systematic way of taking measures that demonstrate to FDA, to your customers, and to consumers that you purchase your imported seafood products from foreign suppliers who routinely practice seafood safety by design, and are in compliance with the U. S. food laws and regulations.

During our inspection, the FDA investigator observed shortcomings in your verification procedures that, upon our preliminary review, appear to be deviations from the requirements of the Seafood HACCP regulations. The FDA investigator also provided you with a copy of the Import Seafood HACCP Report (form FDA 3502), which presents his evaluation of your firm's performance regarding various aspects of the HACCP requirements. The observations of concern to us are as follows:

- You must have product specifications that are designed to ensure that the fish and fishery products you import are not injurious to health, to comply with 21 CFR 123.12(a)(2)(i). However, your firm does not have a product specification for Anchovies in oil imported from [redacted].

- You must implement, document, and maintain records of an affirmative step which ensures that the fish and fishery products you import are processed in accordance with the seafood HACCP regulations, to comply with 21 CFR 123.12(a)(2)(ii) and (c). However, your firm did not perform or document an affirmative step for Anchovies in oil manufactured by one [redacted] supplier.

In addition, the investigator's inspection of your "vinegar" packing operation determined that you were bottling glacial acetic acid, diluted with water to 5%, and labeling it as "WHITE VINEGAR style." Diluted acetic acid is not vinegar and would be considered misleading if so labeled. I have enclosed the FDA policy statement regarding this matter.

We encourage you to make the necessary improvements as soon as possible. However, if you disagree with FDA's assessment, you should explain how your system is complying with the regulations. We understand that there may be more than one way to verify compliance with the Seafood HACCP regulations. In either case, you should respond to this office on this matter within 30 working days of the receipt of this letter. Upon receipt of your response, we will work with you to resolve any outstanding issues associated with your verification plan. In addition, please include any corrective action(s) such as new labeling or procedures you are/will employ in bottling "vinegar." If we do not hear from you, or if your response is inadequate, we will assume that our preliminary conclusions are correct and we will schedule a follow-up inspection for the immediate future.

Your reply relating to these concerns should be directed to Paul A. Boehmer, Compliance Officer.

If you have any questions regarding the implementation of the HACCP regulations, you may contact Darrell Luedtke at our Gurnee, Illinois office, telephone (847) 249-8632, for answers and/or direction towards guidance and sources of training in achieving compliance.

We look forward to working with you to achieve a successful HACCP program.

Sincerely,

\s\
Raymond V. Mlecko
District Director

cc: Andrea J. Mugnolo, Secretary/Treasurer
J.M.C. Ltd. d.b.a. Racconto
2000 Hawthorne St.
Melrose Park, IL 60160